

delay any ruling until further investigation into this matter has been made.

Yours truly,

BILL MAGRUDER,
Vice President, Pharmacy Program.

NATIONAL ASSOCIATION OF
CHAIN DRUG STORES,
Alexandria, VA, April 26, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration,
Rockville, MD.

DEAR DR. KESSLER: On behalf of the National Association of Chain Drug Stores (NACDS), I am writing to strongly urge that the Food and Drug Administration (FDA) recognize pre-GATT patent expiration dates for pharmaceuticals, and allow the approval of ANDAs for generic prescription pharmaceutical preparations where the sponsor of such application has made a "substantial investment" in the product prior to June 8, 1995, the date of implementation of the General Agreement on Tariffs and Trade (GATT). We understand that the FDA is currently considering whether GATT's implementing legislation provides such statutory authority. NACDS believes that it does.

NACDS represents America's chain drug store industry, and includes more than 160 chain companies in an industry that operates 30,000 retail community pharmacies. Chain pharmacy is the largest component of retail pharmacy practice, providing practice settings for more than 66,000 pharmacists. Our membership base fills over 60 percent of the more than two billion prescriptions dispensed annually in the United States.

We understand and support the importance of having generic prescription drugs available to consumers as soon as possible. Everyday, the availability of generic drugs enables the pharmacists who practice in our stores to help reduce overall prescription medication costs for populations that do not have prescription drug insurance. Among those who benefit from access to generic drugs are millions of older Americans and working poor, publicly-funded prescription drug programs such as Medicaid, and other third party prescription drug plans.

The impact that a misapplication of the GATT implementing legislation could have on the American public is significant. A recent study by the PRIME Institute at the University of Minnesota found that GATT provisions could result in an additional \$6 billion in prescription drug expenditures in the United States because of the additional patent protections granted to brand name products, and the relative unavailability of lower-cost generic versions.

In summary, NACDS believes that the GATT agreement should not preclude the manufacturers of generic prescription drugs from bringing their products to market during the period of extended patent protection provided by GATT for brand name prescription drug products.

Sincerely,

RONALD L. ZIEGLER,
President and Chief Executive Officer.

NATIONAL PHARMACEUTICAL ALLIANCE,
Alexandria, VA, April 26, 1995.

Hon. DAVID PRYOR,
U.S. Senate, Washington, DC.

DEAR SENATOR PRYOR: The National Pharmaceutical Alliance (NPA) is an association of over 165 manufacturers and distributors of pharmaceutical preparations for human and veterinary use. Our members are dedicated to providing safe and affordable alternatives to the American public whenever health needs dictate the use of pharmaceutical products.

In December of last year, the congress ratified the Uruguay Round Agreements Act

[P.L. 103-465] (URAA) of the General Agreement on Trade and Tariffs (GATT). This agreement created some fundamental changes to be made in U.S. patent law. The new law provides for patents to be in force 20 years from the date of application as opposed to the historical law of the United States which provided for patents to be in force for 17 years from date of approval. Congress, realizing that such a change would cause a financial hardship on companies that expected to enter the marketplace at the expiration of the old patent date, provided a remedy to allow competing products on the market.

Under H.R. 5110, the implementing language of GATT, companies that could show that a substantial investment had been made in a product could enter the marketplace at the pre-GATT expiry date. The respective companies then would work out an "equitable remuneration" during the life of the patent extension. This remedy will work for every industry except the generic pharmaceutical industry due to its regulation by the Food and Drug Administration. Since approvals for Abbreviated New Drug Applications (ANDAs) are governed by the Drug Price Competition and Patent Term Restoration Act of 1984, known as Hatch/Waxman, failure to change its provisions could prevent the FDA from granting approvals until after the patent extension has expired. We do not believe that Congress intended to treat the drug industry differently than other industries.

If the 109 generic pharmaceutical products inversely affected by GATT are kept off the market, the result could be an increased cost to the American consumer of over \$6 billion and a cost of over \$1.2 billion to Federal and State governments in higher Medicare and Medicaid costs. In 1995 alone, drugs such as alclometrasone dipr. (Alclovat), captopril (Capoten), and ranitidine HCl (Zantac) could be unavailable to consumers in a generic version. Zantac alone could represent an additional cost to the consumers in excess of \$1 billion during the time of the patent extension. At a time when both healthcare costs and government budgets are strained to the limit, it makes no sense for government to take any action that would fuel the growth in these expenditures.

In the ten years since its passage, the Hatch/Waxman legislation has done remarkably well at balancing the interests of proprietary drug companies and the generic drug industry. The public also has come to not only expect, but to rely upon, timely access to high quality, low cost alternatives to monopolistic priced name brand drugs.

NPA is pleased to see that members of Congress, such as yourself, are taking steps to correct this inequity in the law. Your actions are to be applauded and your decision to stand up for the American consumer is appreciated.

Sincerely,

CHRISTINE SIZEMORE,
Executive Director.

INTERSTATE TRANSPORTATION OF MUNICIPAL SOLID WASTE ACT

The Senate resumed consideration of the bill.

The PRESIDING OFFICER (Mr. THOMAS). The pending business is the Jeffords amendment No. 867.

The Senator from Michigan.

Mr. LEVIN. Mr. President, I ask unanimous consent I be allowed to proceed as in morning business for 3 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator may proceed.

THE NATIONAL RIFLE ASSOCIATION

Mr. LEVIN. Mr. President, our friend from Arkansas has brought to our attention the fact that former President Bush has decided to resign from the National Rifle Association because of its refusal to repudiate some statements which were made by a vice president of NRA in a fundraising letter. I join Senator PRYOR in commending former President Bush for his action. I am sure it is a difficult one for the President, as a decades-long member of the NRA and as someone who believes in so many of its programs and efforts to protect rights under the second amendment.

But what President Bush reacted to is what I think most Americans who have read this letter reacted to, which is a statement by Mr. LaPierre, among others, that the Clinton administration has authorized law enforcement personnel to murder law-abiding citizens.

Those are the words in the letter. It is an outrageous allegation about any American President or any American administration. I do not think 1 percent of the members of the NRA believe that the Clinton administration has authorized its agents, its Treasury agents, its FBI agents, its law enforcement agents, to murder law-abiding citizens. I wrote a letter to Tom Washington, whom I know. He is a resident of Michigan who was president of the National Rifle Association, urging him to retract that statement and some other allegations in that letter which are, I think, equally offensive, but at least that statement.

In his response to me, which I put in the RECORD yesterday or the day before yesterday, he really did not respond to the request. He simply acknowledged that sometimes fundraising letters have exaggerated rhetoric. But this is not a case of just exaggerated rhetoric. This is an allegation by one of the Nation's largest organizations that this administration has given the go-ahead to law enforcement personnel to murder—I am using the word murder because that is exactly the word that they used; indeed the letter underlines it, italicizes it, emphasizes it—to murder law-abiding citizens.

I do not think, again, anybody on this floor would think there is truth to that statement. I do not think 1 percent of the members, as I said, of the NRA believes there is truth to that statement. It is that kind of a statement, of a wild statement, of an irresponsible statement by a major organization, which is creating an unacceptable climate in this country, I believe. Is it the only statement? Of course not. Others have made outrageous statements, too. Do they have a right to make that statement under the first amendment? They do. I will defend it.